

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Chen, et al. Art Unit : Unknown  
Serial No. : 10/705,245 Examiner : Unknown  
Filed : November 10, 2003  
Title : RISK ASSESSMENT FOR ADVERSE DRUG REACTIONS

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

## INFORMATION DISCLOSURE STATEMENT

In accordance with the duty of disclosure as set forth in 37 C.F.R. §1.56, Applicants hereby submit the following information in conformance with 37 C.F.R. §§ 1.97 and 1.98. Pursuant to 37 C.F.R. § 1.98, a copy of each of the documents cited is enclosed. However, copies of the listed U.S. patents and U.S. patent application publications are not enclosed since it is no longer required to submit copies of cited U.S. patents and U.S. patent application publications in national patent applications filed after June 30, 2003, according to the July 11, 2003 waiver of the requirement.

### United States Patents/Patent Publications

1. U.S. Patent No. 6,583,139

## Articles

2. Bigby M, Jick S, Jick H, Amdt K. (1986) Drug-induced cutaneous reactions. A report from the Boston Collaborative Drug Surveillance Program on 15,438 consecutive inpatients, 1975 to 1982. *JAMA*. 256(24):3358-3363.
3. Chan SH and Tan T. "HLA and allopurinol drug eruption" *Dermatologica*. 1989, 179(1):32-3.
4. Edwards SG, Hubbard V, Aylett S, Wren D. Concordance of primary generalised epilepsy and carbamazepine hypersensitivity in monozygotic twins. *Postgrad Med J*. 1999, 75(889):680-1.

**CERTIFICATE OF MAILING BY EXPRESS MAIL**

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Date of Deposit

5. Feltkamp TE, Mardjuadi A, Huang F, Chou CT. Spondyloarthropathies in eastern Asia. *Curr Opin Rheumatol.* 2001, 13(4):285-90.
6. Gennis MA, Vemuri R, Burns EA, Hill JV, Miller MA, Spielberg SP. Familial occurrence of hypersensitivity to phenytoin. *Am J Med.* 1991, 91(6):631-4.
7. Green VJ, Pirmohamed M, Kitteringham NR, Gaedigk A, Grant DM, Boxer M, Burchell B, Park BK. Genetic analysis of microsomal epoxide hydrolase in patients with carbamazepine hypersensitivity. *Biochem Pharmacol.* 1995, 50(9):1353-9.
8. Hari Y, Frutig-Schnyder K, Hurni M, Yawalkar N, Zanni MP, Schnyder B, Kappeler A, von Greyerz S, Braathen LR, Pichler WJ. T cell involvement in cutaneous drug eruptions. *Clin Exp Allergy.* 2001, 31(9):1398-408.
9. Khan MA. Update: the twenty subtypes of HLA-B27. *Curr Opin Rheumatol.* 2000, 12(4):235-8.
10. Lazarou J, Pomeranz BH, Corey PN. (1998) Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. *JAMA.* 279(15):1200-1205.
11. Leeder JS. Mechanisms of idiosyncratic hypersensitivity reactions to antiepileptic drugs. *Epilepsia.* 1998, 39 Suppl 7:S8-16.
12. Naisbitt DJ, Britschgi M, Wong G, Farrell J, Depta JP, Chadwick DW, Pichler WJ, Pirmohamed M, Park BK. Hypersensitivity reactions to carbamazepine: characterization of the specificity, phenotype, and cytokine profile of drug-specific T cell clones. *Mol Pharmacol.* 2003, 63(3):732-41.
13. Pichler WJ, Zanni M, von Greyerz S, Schnyder B, Mauri-Hellweg D, Wendland T. High IL-5 production by human drug-specific T cell clones. *Int Arch Allergy Immunol.* 1997, 113(1-3):177-80.
14. Pirmohamed M, Lin K, Chadwick D, Park BK. TNF $\alpha$  promoter region gene polymorphisms in carbamazepine-hypersensitive patients. *Neurology.* 2001, 56(7):890-6.
15. Roujeau JC, Bracq C, Huyn NT, Chausalet E, Raffin C, Duedari N. HLA phenotypes and bullous cutaneous reactions to drugs. *Tissue Antigens.* 1986, 28(4):251-4.
16. Roujeau JC, Huynh TN, Bracq C, Guillaume JC, Revuz J, Touraine R. Genetic susceptibility to toxic epidermal necrolysis. *Arch Dermatol.* 1987, 123(9):1171-3.

17. Roujeau JC. The spectrum of Stevens-Johnson syndrome and toxic epidermal necrolysis: a clinical classification. *J Invest Dermatol.* 1994, 102(6):28S-30S.
18. Roujeau JC, Stern RS. Severe adverse cutaneous reactions to drugs. *N Engl J Med.* 1994, 331(19):1272-85.
19. Roujeau JC, Kelly JP, Naldi L, Rzany B, Stern RS, Anderson T, Auquier A, Bastuji-Garin S, Correia O, Locati F, et al. Medication use and the risk of Stevens-Johnson syndrome or toxic epidermal necrolysis. *N Engl J Med.* 1995, 333(24):1600-7.
20. Shirato S, Kagaya F, Suzuki Y, Joukou S. Stevens-Johnson syndrome induced by methazolamide treatment. *Arch Ophthalmol.* 1997, 115(4):550-3.
21. Svensson CK, Cowen EW, Gaspari, AA. (2000) Cutaneous drug reactions. *Pharmacol Rev.* 53(3):357-379.
22. Wolkenstein P, Carriere V, Charue D, Bastuji-Garin S, Revuz J, Roujeau JC, Beaune P, Bagot M. A slow acetylator genotype is a risk factor for sulphonamide-induced toxic epidermal necrolysis and Stevens-Johnson syndrome. *Pharmacogenetics.* 1995, 5(4):255-8.
23. Yates CR, Krynetski EY, Loennechen T, Fessing MY, Tai HL, Pui CH, Relling MV, Evans WE. Molecular diagnosis of thiopurine S-methyltransferase deficiency: genetic basis for azathioprine and mercaptopurine intolerance. *Ann Intern Med.* 1997, 126(8):608-14.

This Information Disclosure Statement is being submitted within three (3) months of the filing date or before any office action is issued. Consequently, no fee is required pursuant to 37 C.F.R. §1.97(b).

By citing the above references, Applicants do not acquiesce or admit that any of these documents is "prior art" under 35 U.S.C. Applicants specifically reserve the right, where appropriate, to antedate any of the cited documents by an appropriate showing under 37 C.F.R. §1.131, §1.604, §1.608 or any other suitable means.


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Attorney's Docket No.: 16743-003001 / 12A-920716

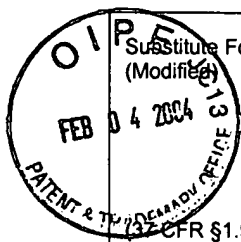
To assist the Examiner, the documents are listed on the attached form PTO-1449. It is respectfully requested that an Examiner initialed copy of this form be returned to the undersigned. Please apply any charges or credits to Deposit Account No. 06-1050.

Respectfully submitted,

Date: Feb. 3, 2004

  
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 Substitute Form PTO-1449  
(Modified)

 U.S. Department of Commerce  
Patent and Trademark Office

 Attorney's Docket No.  
16743-003001 /  
12A-920716

 Application No.  
10/705,245

**Information Disclosure Statement  
by Applicant**  
(Use several sheets if necessary)

Applicant

Chen, et al.

Filing Date

November 10, 2003

Group Art Unit

Unknown

**U.S. Patent Documents**

Examiner Initial	Desig. ID	Document Number	Publication Date	Patentee	Class	Subclass	Filing Date If Appropriate
	AA	6,583,139	06/24/2003	Thorsett, et al.			
	AB						
	AC						
	AD						

**Foreign Patent Documents or Published Foreign Patent Applications**

Examiner Initial	Desig. ID	Document Number	Publication Date	Country or Patent Office	Class	Subclass	Translation	
							Yes	No
	AE							
	AF							
	AG							
	AH							

**Other Documents (include Author, Title, Date, and Place of Publication)**

Examiner Initial	Desig. ID	Document
	AI	Bigby M, Jick S, Jick H, Amdt K. (1986) Drug-induced cutaneous reactions. A report from the Boston Collaborative Drug Surveillance Program on 15,438 consecutive inpatients, 1975 to 1982. <i>JAMA</i> . 256(24):3358-3363.
	AJ	Chan SH and Tan T. "HLA and allopurinol drug eruption" <i>Dermatologica</i> . 1989, 179(1):32-3.
	AK	Edwards SG, Hubbard V, Aylett S, Wren D. Concordance of primary generalised epilepsy and carbamazepine hypersensitivity in monozygotic twins. <i>Postgrad Med J</i> . 1999, 75(889):680-1.
	AL	Feltkamp TE, Mardjuadi A, Huang F, Chou CT. Spondyloarthropathies in eastern Asia. <i>Curr Opin Rheumatol</i> . 2001, 13(4):285-90.
	AM	Gennis MA, Vemuri R, Burns EA, Hill JV, Miller MA, Spielberg SP. Familial occurrence of hypersensitivity to phenytoin. <i>Am J Med</i> . 1991, 91(6):631-4.
	AN	Green VJ, Pirmohamed M, Kitteringham NR, Gaedigk A, Grant DM, Boxer M, Burchell B, Park BK. Genetic analysis of microsomal epoxide hydrolase in patients with carbamazepine hypersensitivity. <i>Biochem Pharmacol</i> . 1995, 50(9):1353-9.
	AO	Hari Y, Frutig-Schnyder K, Hurni M, Yawalkar N, Zanni MP, Schnyder B, Kappeler A, von Greysen S, Braathen LR, Pichler WJ. T cell involvement in cutaneous drug eruptions. <i>Clin Exp Allergy</i> . 2001, 31(9):1398-408.
	AP	Khan MA. Update: the twenty subtypes of HLA-B27. <i>Curr Opin Rheumatol</i> . 2000;12(4):235-8.
	AQ	Lazarou J, Pomeranz BH, Corey PN. (1998) Incidence of adverse drug reactions in hospitalized patients: a meta-analysis of prospective studies. <i>JAMA</i> . 279(15):1200-1205.

Examiner Signature

Date Considered

EXAMINER: Initials citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Substitute Form PTO-1449 (Modified) <b>Information Disclosure Statement</b> by Applicant (Use several sheets if necessary) (37 CFR § 1.98(b))		U.S. Department of Commerce Patent and Trademark Office	Attorney's Docket No. 16743-003001 / 12A-920716	Application No. 10/705,245
			Applicant Chen, et al.	
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<b>Other Documents (include Author, Title, Date, and Place of Publication)</b>				
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	AR	Leeder JS. Mechanisms of idiosyncratic hypersensitivity reactions to antiepileptic drugs. <i>Epilepsia</i> . 1998, 39 Suppl 7:S8-16.		
	AS	Naisbitt DJ, Britschgi M, Wong G, Farrell J, Depta JP, Chadwick DW, Pichler WJ, Pirmohamed M, Park BK. Hypersensitivity reactions to carbamazepine: characterization of the specificity, phenotype, and cytokine profile of drug-specific T cell clones. <i>Mol Pharmacol</i> . 2003, 63(3):732-41.		
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	AW	Roujeau JC, Huynh TN, Bracq C, Guillaume JC, Revuz J, Touraine R. Genetic susceptibility to toxic epidermal necrolysis. <i>Arch Dermatol</i> . 1987, 123(9):1171-3.		
	AX	Roujeau JC. The spectrum of Stevens-Johnson syndrome and toxic epidermal necrolysis: a clinical classification. <i>J Invest Dermatol</i> . 1994, 102(6):28S-30S.		
	AY	Roujeau JC, Stern RS. Severe adverse cutaneous reactions to drugs. <i>N Engl J Med</i> . 1994, 331(19):1272-85.		
	AZ	Roujeau JC, Kelly JP, Naldi L, Rzany B, Stern RS, Anderson T, Auquier A, Bastuji-Garin S, Correia O, Locati F, et al. Medication use and the risk of Stevens-Johnson syndrome or toxic epidermal necrolysis. <i>N Engl J Med</i> . 1995, 333(24):1600-7.		
	AAA	Shirato S, Kagaya F, Suzuki Y, Joukou S. Stevens-Johnson syndrome induced by methazolamide treatment. <i>Arch Ophthalmol</i> . 1997, 115(4):550-3.		
	ABB	Svensson CK, Cowen EW, Gaspari AA. (2000) Cutaneous drug reactions. <i>Pharmacol Rev</i> . 53(3):357-379.		
	ACC	Wolkenstein P, Carriere V, Charue D, Bastuji-Garin S, Revuz J, Roujeau JC, Beaune P, Bagot M. A slow acetylator genotype is a risk factor for sulphonamide-induced toxic epidermal necrolysis and Stevens-Johnson syndrome. <i>Pharmacogenetics</i> . 1995, 5(4):255-8.		
	ADD	Yates CR, Krynetski EY, Loennechen T, Fessing MY, Tai HL, Pui CH, Relling MV, Evans WE. Molecular diagnosis of thiopurine S-methyltransferase deficiency: genetic basis for azathioprine and mercaptopurine intolerance. <i>Ann Intern Med</i> . 1997, 126(8):608-14.		

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